Message

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Sent: 9/6/2016 3:32:58 PM
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Subject: News Articles (For EPA Distribution Only)

BNA DAILY ENVIRONMENT REPORT ARTICLES

White House Launches Review of EPA Vapor Intrusion Rule

Posted: Sep 6, 2016, 9:44 AM EDT

By Brian Dabbs

An EPA final rule to add vapor intrusion to Superfund listing criteria is under review at the White House Office of Management and Budget.

The rule (RIN:2050-AG67), received by OMB Sept. 2, would give the EPA authority to consider vapor intrusion, the process of volatile compounds migrating through sub-surface groundwater or soil to air in above-ground structures, when determining whether to add a contaminated site to the Superfund National Priorities List.

Exposure to that migration can cause health damages depending on the chemicals at play.

The White House predicts final approval by January.

FDA Bans Triclosan, Other Antibacterials in Consumer Products

Snapshot

• Soaps containing 19 antibacterial chemicals can no longer be sold over the counter

• FDA says industry did not provide data proving they are safe and effective

By David Schultz

Sept. 2 — Hand and body washing products containing triclosan, triclocarban and 17 other antibacterial chemicals can no longer be sold over the counter after the FDA determined they may be harmful and ineffective.

The final rule establishing the ban on these chemicals means the likely end to their use in hundreds of consumer products. Theresa Michele, head of the Food and Drug Administration's nonprescription drug evaluation division, said the cleaning industry did not or could not produce data showing that the benefits of these chemicals outweigh their potential health risks.

"Millions of Americans use antibacterial products every day," Michele said in a Sep. 2 press conference, "but these products may not provide any benefits beyond soap and water."

The runoff of these chemicals into water supplies has been a major concern for environmental activists because of their potential effects on the endocrine systems of aquatic animals. However, Michele said the FDA did not consider the environmental effects of the chemicals when making its decision, but instead looked only at their efficacy and their ability to affect human health.

Three Exceptions

Manufacturers will have a year from Sept. 6, when the final regulation will be published in the Federal Register, to phase these chemicals out of their products. Michele said roughly 40 percent of the more than 2,000 personal cleaning products on the market contain at least one of the 19 chemicals affected by the new regulation, which was first proposed in 2013. She said companies could reintroduce them into the marketplace only if they undergo the FDA's screening for prescription drugs.

Not included in the 19 chemicals affected by this regulation are three other antibacterial agents: benzalkonium chloride, benzethonium chloride and chloroxylenol. Michelle said the FDA is giving the personal cleaning product industry more time to submit safety and efficacy data on these chemicals before it takes action on them.

The American Cleaning Institute, which represents companies that make products containing these chemicals, said in a statement that its members will work to provide FDA with the data it needs. But it also said the FDA already has data on the other 19 antibacterial chemicals that shows they are safe and effective.

The FDA's actions only apply to consumer-grade washing products. The 19 chemicals are still permitted for use in alcohol-based hand sanitizers, which are used without water, and in antibacterial products that are used in health care settings.

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A Proposition 65 Violation May Be Lurking in Your Cash Register or ATM Receipt

By Meredith Jones-McKeown and Chris Mackay

Meredith Jones-McKeown is a partner in Sheppard Mullin's San Francisco office with extensive experience defending against Prop. 65 actions based on dozens of chemicals against all the major Prop 65 plaintiffs' firms.

Chris Mackay, senior managing toxicologist at Intertox Inc., helps companies analyze whether exposures above the Prop. 65 Maximum Allowable Dose Level or No Significant Risk Level have occurred. Intertox fields expertise to help manage supply chains to ensure Prop. 65 violations do not occur.

Businesses operating in California have long been aware of the perils of utilizing any of the almost 1,000 chemicals identified by the state of California as potentially causing cancer or reproductive harm under California's "Proposition 65." Consumer-facing businesses have learned to identify high-risk Prop 65 targets: soft, flexible plastics; faux and colored leathers; and any kind of brass or metal that may contain lead or other heavy metals. If they don't, scores of Prop 65 "bounty-hunters" are waiting in the wings to seek penalties and attorney's fees from businesses when they are caught including these chemicals in their products without a compliant warning label.

But since California typically leads the way on consumer regulations, even businesses that don't operate in California should be aware of a recent addition to the Prop 65 list: bisphenol A, or "BPA." Consumer advocates have long voiced concerns about the use of BPA in baby bottles, as a liner for canned goods, and in other plastics and products. And as of May 11, 2016, BPA has been added to the Prop 65 list, so many businesses are scrambling to eradicate its use from these known sources. But one source may come as a surprise: BPA may be lurking in your cash register receipts and other thermal papers.

The Addition of BPA to the Proposition 65 Chemical List. Effective May 11, 2016, the California Office of Environmental Health Hazard Assessment (OEHHA) added BPA to the list of Proposition 65 chemicals known

to the state of California to cause reproductive harm. BPA commonly exists in certain plastics and as a liner for canned foods. But many do not realize that thermal paper (commonly used in printing machines such as cash registers, credit card machines, ATMs and automated ticket printers due to the fact that it does not require ink stock) is also likely to contain BPA—and businesses that fail to phase out the use of BPA-containing thermal paper before May 11th will eventually run the risk of receiving a Proposition 65 Notice of Violation from the plaintiffs' bar. Under Prop 65, businesses have a one-year grace period after the chemical is listed to achieve compliance.

Thermal Paper Technology. The technology of thermal-sensitive paper is straightforward. Normal paper is coated with an ink in a form that has little color at neutral or high pH, but becomes vivid at low pHs. These inks are commonly made with leuco dyes that demonstrate this pH-dependent color change. The paper is then sequentially coated with a thin layer of a temperature-sensitive polymer and a solid-state acid, which acts as a developer. When the paper is heated by the printer head, the polymer melts and the dye and acid combine, the pH of the ink drops, and inks shifts to the colored form. When the paper cools back to room temperature, the thermal polymer condenses over the visible ink, thereby preserving the writing.

Why BPA is Commonly Used in Thermal Paper. In order to function correctly, the acid component of the thermal dye must be solid with moderate water solubility, chemically stable within a large range of temperatures, and possess a low vapor pressure. BPA is one of the few chemicals that meet these criteria, and it provides the additional benefit of being low cost.

Rationale for Adding BPA to the Proposition 65 Chemical List. The toxicology of BPA is complex and its effects on humans are unknown although a substantial number of animal studies have examined it. BPA has been classified as a weak estrogenic mimic, meaning that it produces effects similar to the female sex hormone estrogen. Binding studies with BPA and the classical estrogen receptors suggest its activity is 1,000 to 10,000 times less than estrogen. However, some animal studies show impacts at lower concentrations. Some researchers have opined that BPA may act as a selective estrogen receptor modulator (SERM), while other researchers have advanced alternative theories.

MADL for Reproductive Impacts.OEHHA has promulgated a dermal MADL of BPA of 3 ug/day effective October 1, 2016. This is extremely conservative and may not be supported by data. Studies reported by the National Toxicology Program suggest that a more appropriate MADL would be on the order of 150-250 µg/day.

Concern about Dermal Uptake from Thermal Paper. Because BPA in thermal paper is present in its monomer form, some studies have suggested that it is more available for transfer to people than BPA trapped in a polymer; one academic study published in 2010 reports that a single 5 second contact by two fingers resulted in the average transfer of 1.2 µg (~0.22 µg/cm) of BPA during testing. The study also reported that the transfer amount increased by about 10 times when the fingers were moistened. Interestingly, multiple exposures did not increase the BPA concentration on the skin nor did longer holding periods (60 seconds compared to 5 seconds). This breaks down to an exposure of 3 µg/day (0.05 µg/kg-day) for the incidental user (i.e. consumer) and about 15.8 µg/day (0.24 µg/kg-day) for the occupational user (e.g. sales clerk).

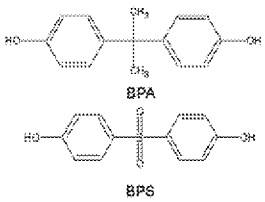
Problems Coming into Compliance. With the finalization of the 3 µg/day dermal MADL, there is an urgent need to remove all BPA-containing thermal paper from the market. Proposition 65 prohibits exposing an

individual to a listed chemical without first giving a clear and reasonable warning. The warning must be reasonably calculated, considering the alternative methods available under the circumstances, to make the warning message available *prior* to exposure. Since exposure to the receipt is automatic for every customer who receives a receipt, traditional Proposition 65 warning systems may not be sufficient to avoid liability for alleged exposures.

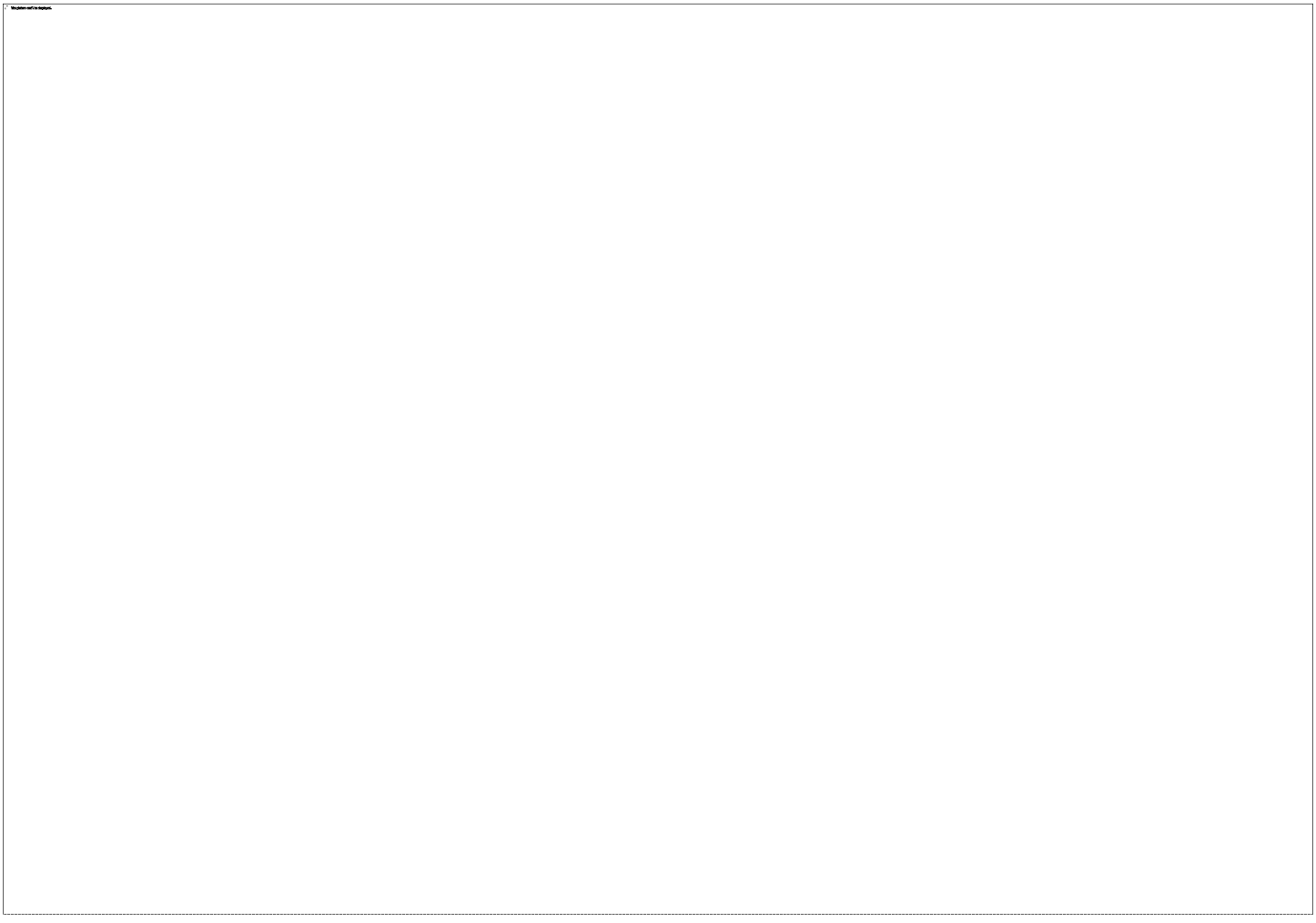
Alternative Materials for Use in Thermal Papers. BPA is not the only possible acid that can be used in thermal paper. The Environmental Protection Agency (EPA) evaluated the hazard levels of 19 different alternatives to BPA that can be used in thermal paper, although "no clearly safer alternatives" were identified in the report. Substitute materials include sulfonyl ureas or substituted salicylic acids, such as zinc di-tert-butylsalicylate. Another alternative commonly used in thermal paper is bisphenol S (BPS); however, because BPS itself has been implicated as a potential endocrine disruptor, it too may face limitations in the near future.

Cost Considerations of Alternative Materials in Thermal Paper. Economically viable chemical substitutes for BPA in thermal paper would include those that are easy to process and cost-effective to integrate into existing products. The Danish Environmental Protection Agency published a report confirming that five of the 19 chemical alternatives identified by the EPA were on the European market as developers in thermal paper. These alternatives have a financial benefit to companies because they can be used in existing thermal printers without adjustments. However, all five of these alternatives are still more expensive than BPA; BPS-based thermal paper is the most common and cheapest alternative at 5 percent to 10 percent more expensive, and Pergafast-based thermal paper is the priciest alternative at 10 percent to 25 percent more expensive. In addition to the higher costs of these alternative chemicals, substituting the developer requires significant adjustments to the manufacturing process and chemistry of the paper. Like the EPA study, this study also could not confirm that these alternatives were healthier than BPA. Where compatibility is not available, companies may need to modify their processes, and potentially purchase new equipment. Other considerations include the handling, disposal, and treatment costs of these substitute materials. Substitution decisions should be seen as long-term investments, and companies should anticipate using any chemical replacement for many years to come, with consideration of future regulatory actions as well as market trends.

Alternatives to Thermal Paper. Alternatives to thermal paper may be considered for substitution, including alternative printing systems to thermal paper, and the use of electronic or digital receipts (e-receipts). The EPA report cautioned that alternative printing systems should be evaluated for performance, cost, and hazard, and the Danish EPA report called these systems "outdated." These products may also be more expensive because they require ribbons, inks, or toner cartridges, and typically have higher maintenance costs. E-receipts, in addition to being environmentally friendly, generate financial benefits by reducing manufacturer, transport, storage, and disposal costs, but also require additional data storage devices, electronic products, and peripherals that make their implementation and use more expensive. Today, more than one-third of retail businesses in the U.S. offer e-receipt options, and the practice is a growing trend. Should companies offer the option of either an e-receipt or a paper receipt at the counter, it may be possible to warn consumers who elect a paper option about the risks of BPA in those receipts, prior to their exposure.



Chemical structure of bisphenol A (top) and the related bisphenol S (bottom). BPA is a common chemical used in the adhesives and plastic industries. It is the common monomer in epoxy adhesives (the resin component) and is also used as a monomer high impact polycarbonates used to make reusable bottles, safety glasses, and CD/DVDs. Other advanced plastics such as polyether- and polyether ether ketones as well as polysulfonates may contain BPA. BPA may also be found in PVC and vinyl (softened PVC), where it is sometimes included in the product as both a polymerization terminator and as an antioxidant.



Daily BPA exposure based on urinary metabolite. The 2003-2004 National Health and Nutrition Survey (NHANES), performed annually by the Centers for Disease Control, measured BPA metabolites in participants and back-calculated exposures by age group. Bars represent the 25th (black), 50th (red), and 95th (green) percentile estimates from the 2003-2004 NHANES survey. The current draft MADL BPA falls in the 25-50th percentile.

Fuel Oxygenate Harms Kidneys, May Cause Cancer: EPA Draft

Snapshot

• Agency's draft analysis finds a fuel oxygenate harms kidneys and could cause liver tumors

• EPA, nonagency scientists to discuss the chemical's effect on liver during Oct. 23 meeting

• Comments on EPA's draft assessment accepted through Oct. 31

By Pat Rizzuto

Sept. 2 — A former fuel oxygenate found in some gasoline-contaminated soils and groundwater harms kidneys and could cause cancer, according to a draft Environmental Protection Agency assessment.

The EPA released Sept. 1 a draft toxicological review of ethyl tertiary butyl ether (ETBE) that concludes the chemical shows "suggestive evidence of carcinogenic potential" based on liver tumors found in male rats. Studies of male and female rats also showed ingestion or inhalation of ETBE could harm kidneys, the agency said.

Petroleum companies added ETBE to gasoline from 1990 to 2006 to reduce pollution in vehicular exhaust, the agency said. Other oxygenates—notably methyl tert-butyl ether (MTBE)—were more commonly used, however, the EPA said. The use of these oxygenates in the U.S. has ceased, largely in response to their potential to contaminate groundwater, the agency said.

The EPA's draft assessment is being conducted under its Integrated Risk Information System (IRIS) program. If issued as a final analysis, the assessment's conclusions about the hazards of ETBE and the doses at which those hazards could manifest will be entered into the IRIS database. The EPA's regulatory offices, states, environmental consultants and regulators in other countries use information from the IRIS database to conduct risk analyses that underlay regulatory decisions.

Information from a final ETBE analysis could be used as part of hazardous waste and groundwater cleanups. California maintains a database of contaminated sites that reported ETBE in groundwater at 607 sites between 2010 and 2013, the draft assessment said.

Information about the scope of ETBE contamination across the U.S. is incomplete, however. Only 13 states routinely analyze environmental media for the oxygenate at fuel contaminated sites, and fuel-related cleanups are largely done by states, the EPA said.

The agency will host a public science meeting Oct. 23 to discuss ETBE's liver tumors in particular as the relevancy of some rodent liver tumors for humans is debatable. The agency will accept comments on the draft assessment through Oct. 31.

Ingesting, Inhaling ETBE

No human studies are available to evaluate the health effects of ETBE following ingestion or inhalation, the EPA said.

The agency's IRIS program has not issued a final assessment of ETBE before, although it published a draft assessment in 2009. That draft assessment also proposed to classify the oxygenate as having "suggestive evidence of carcinogenic potential."

That assessment, however, was among four IRIS chemical evaluations the EPA placed on hold after the U.S. National Toxicology Program and an Italian research organization, the Ramazzini Institute, reached divergent opinions on cancer data the institute generated.

The EPA's new draft assessment proposes a reference dose of 0.5 milligram per kilogram bodyweight per day. The proposed reference dose drew heavily on a study conducted since 2009, when the EPA said available data was too uncertain to estimate a reference dose, which is a dose the agency presumes humans, including vulnerable populations, could ingest every day of their life without harm.

The agency's new draft assessment proposes a reference concentration of 9 milligrams per cubic meter of air (mg/m3), also based on research conducted since 2009. That reference concentration presumes people could inhale more of ETBE without harm than the agency estimated in 2009, when it proposed a 0.006 mg/m3 reference concentration.

Global ETBE Demand

Lyondell Chemical Co. and one other company—which claimed its name to be confidential business information—were the two U.S. manufacturers of ETBE in 2011, the most recent year for which U.S. production data is available from the EPA. The agency withheld ETBE's national production volume information to protect proprietary information.

The U.S. produced 25 percent of the global demand for ETBE in 2012, the EPA's draft assessment said. Western Europe consumes the most with use in Eastern Europe and Japan also relatively high, the agency said.

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For More Information

Details on EPA's Oct. 23 public science meeting are available at http://src.bna.com/igM. Comments on EPA's draft assessment should be marked Docket ID No. EPA-HQ-ORD-2009-0229 and filed via http://www.regulations.gov.

PCBs Ordered Out of Malibu School District

Snapshot

- Permanent injunction compels California school district to stick with plan to eradicate PCB risks
- If 2019 repair deadline isn't met, affected structures can't be used

By Bruce Kaufman

Sept. 2 — Two schools in Malibu, Calif., must remove PCB-containing materials by the end of 2019, the Central District of California ruled Sept. 1 (*Am. Unites for Kids v. Lyon*, 2016 BL 287065, C.D. Cal., No. CV 15-2124 PA, 9/1/16).

The permanent injunction is intended to force the Santa Monica Malibu Unified School District to strictly follow existing plans to replace and renovate pre-1979 buildings.

It follows a May bench trial in the U.S. District Court for the Central District of California.

The order requires that all window and door systems, including the surrounding caulk, at Juan Cabrillo Elementary School and Malibu Middle and High School be replaced by Dec. 31, 2019.

This approach is a "reasonable and appropriate remedy" for violating the Toxic Substances Control Act, the court said.

The ruling also winnowed the number of plaintiffs in the suit.

Plaintiff Public Employees for Environmental Responsibility, a non-profit organization that "advocates for public employees concerned with environmental issues," lacks organizational standing because its affidavit was filed by a group "supporter" rather than a group "member," the court said.

A second advocacy group, America Unites for Kids, remains a plaintiff.

Judge Percy Anderson wrote the decision.

The defendants are represented by Pillsbury Winthrop Shaw Pittman.

Plaintiffs' attorneys include Nagler & Associates.

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For More Information

The opinion is available at http://www.bloomberglaw.com/public/document/Am_Unites_for_Kids_v_Lyon_No_CV_152124_PA_AJWx_2016_BL_287065_CD_.

INSIDEEPA.COM ARTICLES

EPA Urged To Clarify Plan For Prioritizing Chemical Reviews Under TSCA

Chemical industry groups are urging EPA to clarify its plans for implementing a mandate under the revised Toxic Substances Control Act (TSCA) for designating substances as either high or low priority for review, including how it will apply to new chemicals and what the agency will do when there is inadequate safety data for a substance.

Chemical Manufacturers Charge EPA's TSCA Rules Encroach On OSHA

Chemical solvent producers are pushing back against pending EPA rules restricting certain chemical uses to protect against workplace and consumer exposures, arguing in White House meetings that EPA's rules encroach on the Occupational Safety and Health Administration's (OSHA) jurisdiction, and petitioning the Consumer Product Safety Commission (CPSC) to bolster consumer protections before EPA does.

Industries, Advocates Query EPA's Plan For TSCA Review Rule Definitions

Groups representing major industrial sectors and environmentalists are querying how EPA plans to define key terms for its pending rule under the revised Toxic Substances Control Act (TSCA) to prioritize chemicals for risk assessment, including "susceptible subpopulations" and how to satisfy a statutory mandate for scientific integrity.

EPA Weighs Updating Lead Dust And Soil Hazard Standards

EPA is considering potential revisions to its lead hazard standards as it reviews lead hazard control data collected by the Department of Housing and Urban Development (HUD), agency toxics chief James Jones recently told two Democratic senators who have been pressing for tightened standards for dust and soil.

EPA Moves Ahead With Synthetic Turf Study Despite Reviewers' Concerns

EPA and other federal agencies have finalized their study protocol for investigating the potential human health risks of exposure to recycled tire crumb rubber used in many synthetic turf playing fields and have begun sampling at selected fields despite concerns from some peer reviewers that the research is too rushed and limited to provide clear answers.

EPA's Latest Draft ETBE Risk Review Echoes Criticized 2009 Assessment

EPA is floating a new draft assessment of the human health risks of the fuel oxygenate ethyl tertiary butyl ether (ETBE) seven years after release of an earlier draft, criticized by industry groups and others for relying on a contested study from an Italian laboratory for its cancer review -- although the new analysis largely echoes the 2009 draft.

CHEMICAL WATCH ARTICLES

Inadequate data should yield TSCA high-priority designation

Stakeholders urge EPA not to assume substances are safe until proven otherwise

6 September 2016 / Data, Lautenberg, United States

Chemicals for which adequate data is not available should be presumed high priorities for risk evaluation under reformed TSCA, consumer advocacy and governmental groups have said.

The stakeholder feedback was given to the US EPA during its development of a procedural rule governing how it will:

- prioritise the assessment of existing substances; and
- designate these as high- and low-priority substances.

The rulemaking is one of several deadlines required by the Lautenberg Chemical Safety Act (LCSA), which amends TSCA.

In its comments, Washington State's ecology department said a "pillar" of the prioritisation process must be that the EPA does not include the assumption it used previously that if no data is available, then it assumes a chemical is safe until proven otherwise.

"It is rapidly becoming the international standard that, if no data is available for a chemical, it cannot be used until its impacts upon human health and the environment have been established," said the department.

NGO Environmental Defense Fund (EDF) said "any 'overinclusion' of chemicals in the high-priority category is far more acceptable than a 'false negative' designation of a chemical as a low priority".

The former will be subject to a full risk evaluation before any regulatory decision is made, it said, whereas low-risk designations will remain in place unless new information arises.

Higher bar

As reformed by the LCSA, TSCA defines high-priority substances as those the administration finds an "unreasonable risk of injury to health or the environment" due to its hazard and potential route of exposure under conditions of use.

The law further defines a low-priority substance as one which "based on information sufficient to establish, without consideration of costs or other non-risk factors" does not meet the standard of a high-priority substance.

in its comments the American Chemistry Council (ACC) said Congress did not intend this low-priority designation to be an "extraordinarily high hurdle", provided the EPA deems as sufficient the information supporting the designation.

But the EDF said that demonstrating the absence of harm is an inherently higher bar to clear than to positively demonstrate the potential of harm. It said more data is needed to arrive at a low-priority designation than a high-priority designation.

The statute bars the EPA from requiring a minimum data set for prioritisation purposes. But the EDF pointed out there is nothing in it prohibiting the agency from requiring minimum information as a basis for designating a chemical low-priority.

"Without such a minimum, EPA risks equating *absence of evidence* of harm with absence of (potential) harm," added the NGO.

NGO the Environmental Working Group (EWG) suggested that the agency should not equate low exposures with low risks. "In some cases, particularly with regard to endocrine-disrupting chemicals, low-dose exposures to a chemical can be just as dangerous as, or more dangerous than, high-dose exposures", it said.

The EDF pointed out that the LCSA allows the EPA to revise a low-priority designation. It urged the agency to include in the prioritisation rulemaking 'express authority' for the agency to revisit low-priority substances. And it said under what circumstances it should do this.

The EDF said such authority is clearly needed, given how production or uses of a substance may change over time, and in light of new information that may arise in the future.

Low-priority substances

The EPA is required to designate at least 20 high- and low-priority substances within three and a half years of the LCSA's enactment.

The American Petroleum Institute (API) urged the EPA to move quickly to designate low priority chemicals. And, it added, to "outline timely, scientifically sound, and efficient approaches for designating chemicals or categories of chemicals as low priority".

For identifying low-priority substance candidates, the ACC encouraged the EPA to look beyond the Safer Chemical Ingredient List (Scil).

It proposed the agency look at the substances that were considered for inclusion as work plan chemicals, but were set aside due to lower scores. It also suggested reviewing the 19,000 substances set aside under the Canadian prioritisation process.

The API also proposed that chemicals or groups of chemicals already comprehensively addressed by existing regulations should be considered for low priority, as well as substances exempt for use and exposure reporting under the Chemical Data Reporting (CDR) regulations.

Kelly Franklin

Editor, North America

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- Prioritisation under new TSCA intended to be 'broad'

Further Information:

- Prioritisation docket

European Commission's EDC criteria could impact biocides review programme

6 September 2016 / Biocidal products Regulation, Biocides, Europe

The European Commission has highlighted the challenge of achieving the 2024 biocidal products review programme deadline, alongside implementation of the proposed criteria for identifying biocides with endocrine disrupting chemical (EDC).

During Echa's biocides stakeholders' day on 1 September, DG Sante's Mario Nagtzaam said the review programme is a clear Commission priority, as it forms the basis for the EU's management of biocides.

And speaking to *CW+BiocidesHub* he said it is important to meet the 2024 objective to ensure biocides on the market are safe for human health and the environment system.

Implementation of the proposed EDC criteria for biocides is still under discussion. On 15 June the Commission issued a draft delegated act for biocidal products, along with a draft implementing act for plant protection products, and an overall communication on the EDC impact assessment report .

A group of EU member states experts will discuss the biocides draft before the Commission adopts it. Mr Nagtzaam hopes this will happen this year. It then undergoes scrutiny by the European Council of Ministers and the European Parliament.

He pointed out that once adopted the criteria would be implemented immediately. There will be no transition period.

The EDC criteria are expected to impact 49 substances under review, and 110 already approved active substances.

Mr Nagtzaam said a work programme will be established to deal with integration of the criteria for approved active substances.

Emma Chynoweth

Managing Editor

Further Information:

- Biocides stakeholders' day

EU authorities need to invest in substitution expertise

Lowell report makes ten recommendations to Echa

5 September 2016 / Alternatives assessment & substitution, Europe, REACH, SVHCs

Echa and EU member state authorities have been told they need to "significantly grow" their staff capacity to be able to fully support the substitution of harmful substances with safer alternatives.

The recommendation is one of ten in a report by the Lowell Center for Sustainable Production commissioned by Echa.

Based on a survey of member states, the report – *Improving the identification, evaluation, adoption and development of safer alternatives* – found that of those responding (around half of EU countries), the main obstacles to substitution are:

- lack of information on alternatives; along with
- lack of relevant expertise and resources in companies.

And it cites the ability to conduct technical feasibility and performance assessments as the main challenge for member states' alternatives assessment work.

To resolve the issue of limited expertise, the report says Echa should establish a dedicated group of staff with expertise in:

- chemical hazard evaluation;
- chemistry;

- technical assessment; and
- economic analysis.

This group should provide training and support to other authorities and industry. The agency could also help develop external networks of experts, comprised of academics, consultants and government research institutes.

These networks could be an online resource, the report suggests.

In addition, it says web-based data resources based on REACH dossiers would help with screening and evaluation of alternatives.

Lack of funds

The report notes a 'disconnect' between industry's need to identify alternatives to SVHCs and research into substitutes. It says only three member states engaging in and providing funding for alternatives research.

It recommends Echa coordinate EU and member state grants and private/public partnership funds to invest in innovative research to support the development of alternatives.

To achieve this, Echa could analyse the agencies that offer funding to research and innovation at union and government levels to engage their support.

Collaboration

Sharing of resources and coordination between authorities becomes "a critical priority", the report says.

Echa could create or expand mechanisms for greater supply chain collaboration and engagement. These should include:

- shared performance testing and evaluation; and
- demonstration sites, the report recommends.

An evaluation of existing supply chain partnership and collaboration models at EU and member state levels and mechanisms might enhance supply-chain communication around substitution.

Echa could analyse technical support capacities for SMEs in particular at the EU and member state level (including trade associations) that are engaged in supporting chemical substitution activities.

Another opportunity would be to establish a committee for inter-authority analysis of alternatives and chemical substitution. This could "discuss challenges to substitution, share lessons, open doors to collaboration, provide support to smaller member states and identify concrete projects that could be undertaken across member states".

Further report recommendations include:

- a possible 'safer chemical ingredient' listing programme. This could use REACH data to identify safer alternatives for different functional classes of chemicals;
- more detailed guidance materials to complete analyses of alternatives in applications for authorisation and restriction proposals, outlining minimum components and quality criteria; and
- enhanced analysis of alternatives support and training to improve quality and consistency. Echa could also establish a "certified analysis of alternatives practitioner" programme.

"The findings and recommendations of this report are very interesting and highly valuable to our work to stimulate the replacement of substances of concern by safer alternatives," says Geert Dancet, Echa's executive director.

"I believe that this work lists concrete proposals that regulators and industry should seriously consider to implement.

"Echa will take the recommendations forward with its co-regulators and stakeholder organisations in the coming months."

A second substitution report focusing on industry is being conducted by RPA for DG Environment's strategy for a non-toxic environment. The Lowell report includes some findings from that study.

To find out about safe chemicals management initiatives in Scandinavia, join Chemical Watch's Copenhagen Chemicals Summit 28-29 September.

Luke Buxton

Europe desk editor

Related Articles

- EU lacks resources to support chemical substitution

Further Information:

- Lowell Center report

Industry groups urge EPA to consider substance use under TSCA

NGOs protest factoring 'conditions of use' into prioritisation process

5 September 2016 / Exposure scenarios, Lautenberg, United States

Industry groups have urged the US EPA to focus on the conditions of a substance's use during its prioritisation and risk evaluation under the recently reformed TSCA.

The comments came in response to the EPA's request for feedback on two separate rulemakings it must complete within a year of passage of the Lautenberg Chemical Safety Act (LCSA):

- a rule defining how the agency prioritises substances for assessment; and
- a rule governing the risk evaluation process.

Under the statute, 'conditions of use' are those under which a substance is "intended, known, or reasonably foreseen" to be manufactured, processed, distributed, used, or disposed of.

The Consumer Specialty Products Association (CSPA) said this is important, as it will give the EPA "flexibility and discretion to tailor risk evaluations to relevant conditions of use and not 'all' conditions of use."

The International Fragrance Association (Ifra) North America said the EPA must carefully consider how it defines such a "reasonably foreseen" use of a substance.

The agency should not base prioritisations or evaluations on "any outcome that is physically possible", wrote the trade group.

"If EPA does not exercise judgement and discipline on this issue, every chemical will be a high priority and will require severe restriction."

Real world exposure scenarios

The American Chemistry Council (ACC) encouraged the agency to distinguish between intentional use of a substance in a product and its use as an intermediate during the prioritisation phase.

And it urged soliciting such information from stakeholders early in a substance's candidacy for prioritisation.

On risk evaluation, the ACC said the EPA should not consider exposures that are:

- in violation of Osha workplace limits;
- inconsistent with a product's labelling requirements for safe use; or
- outside exposures from an unintended use of a consumer product.

It also said the agency should not factor in exposure scenarios that are regulated under different federal laws than TSCA.

Ifra commented on the agency's statutory requirement to consider the risk a substance poses to potentially exposed or susceptible subpopulations (Pess). It said the identification of such populations is "intrinsically linked to the reasonably foreseeable uses of a chemical".

The EPA should therefore only consider such populations where problematic exposures are reasonably likely to occur, it wrote.

Inconsistent with statute?

But a coalition of more than 30 NGOs said it was "surprised and troubled" by industry suggestions that a substance's use should factor into the prioritisation process. "This is flatly inconsistent with TSCA", it said.

In separate comments, the Environmental Defense Fund (EDF) said the LCSA is "unambiguous in stating that chemical substances, not particular uses or conditions of use, are to be subject to prioritisation".

And on risk evaluation, the EDF said product misuse or accidental conditions of use should be "reasonably foreseen". And they should be incorporated into risk evaluation.

The broader NGO coalition said that it would be an "impermissible reading" of TSCA to use the risk evaluation scoping process to determine that certain substances do not present an unreasonable risk. And, even if the agency does set aside certain uses during scoping, then it must still consider those exposures.

To ignore incremental exposure from such 'set aside pathways' "undermines the agency's ability to conduct aggregate exposure assessments, thereby leading to a potentially significant understatement of risk", said the coalition.

Kelly Franklin

Editor, North America

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Further Information:

- Prioritisation docket

- Risk evaluation docket

Denmark wants limits for fluorinated substances in food packaging

Pushes EU agenda with new chemical package

5 September 2016 / Denmark, EDCs, Food & drink, Food contact, Halocarbons

Denmark's environment and food minister has called on the European Commission to set maximum levels for fluorinated substances in food packaging.

Esben Lunde Larsen says Denmark will work with France, Germany, Luxembourg and Sweden to push for common legislation on polyfluorinated substances in paper and cardboard food contact materials (FCMs).

Denmark will also monitor imports of articles containing fluorinated substances to identify ways to reduce consumer exposure.

The move is part of a new 'chemicals package', building on Denmar's 2014-2017 chemicals action plan.

"This package raises knowledge about the undesirable substances in everyday consumer items. Some of these substances should be limited or phased out," Mr Larsen said.

From 2016-2017 the new package will also focus on:

- EU regulation of tattoo colours: carrying out a national information campaign to highlight exposure to possible carcinogenic and allergenic substances in coloured tattoo inks;
- better EU regulation: later this year the ministry will host a conference. It aims to set Danish priorities for the EU's strategy for a non-toxic environment in 2050;
- knowledge of combination effects: working on existing efforts to develop a model to calculate combination effects of chemicals. This will be used to estimate total exposure and its consequences; and
- a list of endocrine disruptors.

Related Articles

- Denmark reveals chemicals action plan

Further Information:

- EPA press release (Danish)
- Chemicals package (Danish)

US FDA bans 19 substances from antibacterial soaps

Rule covers triclosan and triclocarbon

5 September 2016 / Biocides, Personal care, Product authorisation, United States

The US Food and Drug Administration (FDA) has issued a final rule banning 19 major antibacterial active ingredients from antiseptic wash products. They include triclosan and triclocarban.

"Manufacturers haven't proven that those ingredients are safe for daily use over a long period of time," the agency says.

And, it adds, they "haven't shown that these ingredients are any more effective than plain soap and water in preventing illnesses and the spread of certain infections."

Manufacturers will have a year to comply with the rule by removing products from the market, or their antibacterial active ingredients.

The 19 substances covered by the rule are:

- cloflucarban;
- fluorosalan;
- hexachlorophene;
- hexylresorcinol;
- 6 individual iodophors (iodine-containing ingredients);
- methylbenzethonium chloride;
- phenol (greater than 1.5%)
- phenol (less than 1.5%);
- secondary amyltricresols;
- sodium oxychlorosene;
- tribromsalan;
- triclocarban;
- triclosan; and
- triple dye.

Under the final rule, the FDA has classified the ingredients as not Generally Recognized as Safe and Effective (GRAS/GRAE) for use in consumer antiseptic wash drug products.

Antiseptic products containing these ingredients will be considered new drugs. Approved new drug applications will be required for them.

Typical antiseptic products covered include:

- liquid;
- foam;
- gel hand soaps;
- bar soaps; and
- body washes.

The agency issued a proposed rule in 2013 requiring manufacturers to submit data demonstrating the safety and effectiveness of certain antibacterial ingredients used in over-the-counter antibacterial washes.

But, it says, either no additional data was submitted, or the data and information submitted were insufficient for the agency to find that these ingredients are GRAS/GRAE.

The FDA has deferred rulemaking for one year on three other ingredients:

- benzalkonium chloride;

- benzethonium chloride; and
- chloroxylenol (PCMX).

This is to allow for the "development and submission of new safety and effectiveness data for these ingredients."

The final rulemaking does not apply to consumer hand sanitisers, hand wipes, antiseptic products used in healthcare settings, and antiseptics used in food handler settings.

Co-founder and president of the NGO the Environmental Working Group Ken Cook praised the announcement. He says it's a "huge victory on behalf of human health and the environment".

But the American Cleaning Institute (ACI) says washing hands with antiseptic soap can help reduce the risk of infection beyond that provided by non-antibacterial soap and water.

"The FDA already has in its hands data that shows the safety and effectiveness of antibacterial soaps," it says.

"Manufacturers are continuing their work to provide even more science and research to fill data gaps identified by FDA."

The ACI says it will submit, in the coming year, additional safety and effectiveness data on the three deferred ingredients.

Kelly Franklin

Editor, North America

Related Articles

- US FDA proposes antibacterial soap rule
- Trade groups oppose US FDA antibacterial soaps proposal

Further Information:

- Final rule (pre-publication copy)
- FDA press release
- FDA consumer update
- EWG statement

Sweden sets out budget for non-toxic living strategy

5 September 2016 / Alternatives assessment & substitution, Food & drink, PFCs, Product testing, Sweden

The Swedish government has announced plans to strengthen its work on non-toxic living.

In its budget for 2017 it will set aside SEK 375m (€39m) for chemical investments. This will cover the period up to 2020.

The money will be directed towards several areas of action, including:

- strengthening environmental monitoring of hazardous chemicals;
- achieving a better understanding of perfluorinated alkyl substances (PFAS), especially in drinking water sources;

- funding for a support centre to replace hazardous substances in chemical products and goods;
- mapping the presence of dangerous substances not yet regulated in the EU; and
- national chemicals agency Kemi achieving shorter pesticide processing times.

The government points out that hazardous substances can cause cancer, allergies or affect reproductivity.

Children are particularly vulnerable, it says, and promises to focus on initiatives aimed at young people.

"A non-toxic environment is one of the most important and challenging tasks in environmental policy," says environment minister Karolina Skog.

The government's initiatives, she says, will further "help reduce the risks of chemicals in everyday life".

Kemi director general Nina Cromnier welcomed the announcement: "with increased knowledge about hazardous chemicals in products it will be easier to replace problematic substances with a better alternative."

Kemi will also be called upon to look at restricting Swedish consumers' non-professional use of chemical pesticides, such as on lawns and in flower beds.

The announcement comes as Sweden pushes on with the five year toxic-free strategy it launched in 2014. The first stage of the plan covered 2015-17.

Related Articles

- Sweden outlines next five years of toxic-free strategy
- Swedish government gives 2015-17 action plan go-ahead

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- Government announcement (Swedish)

ACC questions necessity of California's first priority product designation

TDCPP and TCEP phase out in children's mats already largely underway

2 September 2016 / Alternatives assessment & substitution, Children's products, Halocarbons, United States

Industry groups have called into question the necessity for the first priority product designation proposed under California's Safer Consumer Products (SCP) programme.

This is according to comments submitted to a Department of Toxic Substance Control (DTSC) proposed rulemaking on children's foam-padded sleeping products. This seeks to name as priority products those containing:

- tris(1,3-dichloro-2-propyl) phosphate (TDCPP); or
- tris(2-chloroethyl) phosphate (TCEP).

According to the DTSC, to meet the criteria for a priority product designation, a product-chemical combination must have a potential for:

- exposure to a chemical of concern through use, handling or disposal of a priority product; and
- such an exposure to "contribute to or cause significant or widespread adverse impacts to people or the environment."

But the American Chemistry Council (ACC) says the DTSC's economic impact statement indicates that "many children's products manufacturers no longer use flame retardants in their products".

And the Consumer Specialty Products Association (CSPA) says in its comments that manufacturers have "taken action to remove TDCPP and TCEP in children's foam sleeping mats prior to the promulgation of this proposed regulation."

"If, as of September 2016, there are no products offered for sale in California that contain the flame retardants at issue, it is hard to see how DTSC could conclude that there is current, widespread and significant exposure to justify priority product designation," says the ACC.

It adds the agency should engage industry stakeholders to "review and improve" on product-specific exposure and composition details before the release of proposed priority products. Such a step, it said, may show that a priority product designation is not needed.

"It does not serve the purposes of the statute to proceed with priority product rulemakings where manufacturers have phased out of chemistry," says the ACC.

Economic impact statement

Beyond the product designation, the ACC also says it is deeply concerned with the proposal's economic analysis. The DTSC's economic impact statement (EIS), it says, yielded an "inappropriate and unsupported conclusion".

As noted in the ACC's comments, the EIS states that "it costs less to manufacture polyurethane foam without flame retardants than to produce foam with flame retardants."

But the ACC says such an assessment:

- assumes a comparison of 'material x containing substance y' against 'material x not containing substance y'. This does not factor in possible costs associated with other variables that may be changed to maintain the product function or performance;
- fails to hold the product performance as a constant – that is, children's products with equivalent fire resistance;
- does not address testing costs associated with ensuring the performance and safety of a reformulated product; and
- fails to consider possible impacts to the lifecycle of the product.

The ACC says the DTSC should "consider developing tailored rules for conducting economic and fiscal reviews of subsequent priority product rulemakings that more closely supports the purposes of the SCP programme".

NGOs advocate broader designations

Californians for Toxic-Free Fire Safety, a coalition of NGOs, supported the priority product designation. It says there is a large potential for widespread exposure to TDCPP and TCEP from a variety of consumer products, including children's sleeping products.

But it criticises the narrow scope of the rulemaking. It says it excludes other flame retardants of potential concern, and does not allow for the evaluation of a broader range of children's products.

The DTSC should "ensure that it has the ability to focus on and follow up on problematic classes of chemicals across multiple products to make best use of resources as well as make the biggest impact in protecting Californians' health and environment," it says.

Karl Palmer, branch chief for the SCP programme, says all comments will be reviewed and responded to in writing in the rulemaking package.

If the DTSC decides to make any substantive changes to the rulemaking, it will publish those changes and initiate an additional public comment period.

According to Mr Palmer, the next priority product rulemaking will be for spray polyurethane foam systems with MDI. The DTSC hopes to start the rulemaking later this year.

Kelly Franklin

Editor, North America

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- California agency kicks off first priority product rulemaking

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